Docket No.: 005618.P2977

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:	Examiner: Jonathan M. Foreman
William E. Webler	Art Group: 3736
Serial No.: 10/027,877	
Filed: December 19, 2001	
For: **METHOD & APPARATUS FOR DETERMINING INJECTION DEPTH & TISSUE TYPE**	

PETITION

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Director:

Applicants submit one copy of the following Petition pursuant to 37 C.F.R. § 1.181 for consideration by the Director. Please charge any additional amount due or credit any overpayment to deposit Account No. 02-2666.

STATEMENT OF FACTS

The originally-filed above-referenced Application included 25 claims including two independent apparatus claims (claims 1 and 11) and one independent method claim. Originally-filed independent claim 1 was submitted as follows:

1. An apparatus comprising:

an elongate member having dimensions suitable for insertion into a body;

at least one thermally conductive heating element coupled to a portion of the elongate member, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an anemometry circuitry interface electrically coupled to the heating element.

(App. filed Dec. 19, 2001, claim 1, attached as Exh. A). Originally-filed claim 2, which depended on claim 1, was submitted as follows:

2. The apparatus of Claim 1, wherein the elongate member comprises a needle.

(App. filed Dec. 19, 2001, claim 2, Exh. A). Subsequent prosecution included five Office Actions dated July 3, 2003, February 13, 2004, August 25, 2004, February 25, 2005 and August 11, 2005, and Applicant's response thereto. An Advisory Action dated October 20, 2005 and Applicant's Request for Continued Examination ("RCE") dated October 26, 2005 were subsequently issued and filed, respectively, thereto. Subsequent to the filing of the RCE, continued prosecution included two Office Actions dated January 24, 2006 ("January 24 Office Action", attached as Exh. B) and May 23, 2006, and Applicant's response thereto. An Advisory Action dated October 26, 2006 was issued thereafter.

In the Response to the non-final Office Action dated January 24, 2006 ("January 24 Response"), the following amendments and cancellations of claims 1 and 2, respectively, were requested:

1. (Previously Amended) An apparatus comprising:

~~an elongated member~~ a needle having dimensions suitable for insertion into a body, a distal portion suitable for insertion into tissue, a distal opening, and a lumen

extending from a proximal end to the distal opening and in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening;

a thermally conductive heating element coupled to the distal portion of the elongate member, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an interface to a balanced circuit having the heating element and a variable resistor as resistive circuit elements, wherein the balanced circuit measures a first differential resistance between the heating element and the variable resistor in response to a first condition and a second differential resistance in response to a second condition in circuitry to indicate a change of conditions related to a distance of penetration of the thermally conductive heating element into a tissue.

2. (Canceled.)

(January 24 Response, attached as Exh. C). The Examiner accepted the amendments/cancellations and responded with a final Office Action dated May 23, 2006. (Office Action dated May 23, 2006 ("May 23 Office Action"), attached as Exh. D). In the May 23 Office Action, the Examiner rejected claims 3 and 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for depending on a canceled claim, namely, canceled claim 2.

In the Response to the Office Action dated May 23, 2006 ("May 23 Response"), the following amendments to claims 1, 3 and 4, respectively, were requested:

1. (Currently Amended) An apparatus comprising:

a needle having dimensions suitable for insertion into a body, a distal portion suitable for insertion into tissue, a distal opening, and a lumen extending from a proximal end to the distal opening and in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening;

a thermally conductive heating element coupled to the distal portion of the ~~elongate member~~ needle, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an interface to a balanced circuit having the heating element and a variable resistor as resistive circuit elements, wherein the balanced circuit measures a first differential resistance between the heating element and the variable resistor in response to a first condition and a second differential resistance in response to a second condition in circuitry to indicate a change of conditions related to a distance of penetration of the thermally conductive heating element into a tissue.

2. (Canceled.)

3. (Currently Amended) The apparatus of Claim [[2]] 1, wherein the needle has an outer diameter between 0.009 inches and 0.134 inches.

4. (Currently Amended) The apparatus of Claim [[2]] 1, wherein the needle comprises a material of at least one of stainless steel and ceramic.

(May 23 Response, attached as Exh. E). In response, the Examiner issued an Advisory Action dated October 26, 2006 in which he refused to enter the amendments explaining that "[c]laim 1 recites the new limitation 'needle'." (Advisory Action dated October 26, 2006 ("October 26 Advisory Action"), attached as Exh. F).

Applicant mailed a Notice of Appeal to the Patent Office on November 20, 2006 concurrently herewith.

ARGUMENTS

Applicants respectfully set forth the following points to be reviewed by the Director.

I. Amendment to Claim 1 Should be Entered

Applicant respectfully disagrees with the Examiner's contention that "[c]laim 1 recites the new limitation 'needle'." Pending claim 1 includes at least three elements which begin with the following terms, respectively, "a needle . . ." ("first element"), "a thermally conductive heating element . . ." ("second element") and "an interface . . ." ("third element"). (See May 23 Response, attached as Exh. E). In Response to the non-final Office Action dated January 24, 2006, Applicant substituted the limitation "an elongate member" with "a needle" in the first element, but inadvertently neglected to substitute "the elongate member" with "the needle" in the

second element.[1] (See, January 24 Response, Exh. C). The amendment was accepted by the Examiner, but the Examiner did not remark that the second element was not concurrently amended in his subsequent final Office Action dated May 23, 2006. (See, May 23 Office Action, Exh. D). Thus, the January 24 Response, as filed, technically rendered claim 1 indefinite under 35 U.S.C. § 112, second paragraph. (See, January 24 Response, Exh. C). Therefore, in order to perfect claim 1 in anticipation for appeal, Applicant submitted an amendment to claim 1 in the Response to the final Office Action dated May 23, 2006 substituting "the elongate member" with "the needle" in the second element. (See, May 23 Response, Exh. E). Thus, "needle" in claim 1 is not a new limitation as stated by the Examiner in the October 26 Advisory Action. (See, October 26 Advisory Action, Exh. F).

Moreover, although "a needle" was technically a new limitation introduced in claim 1 in the January 24 Response, the limitation was never new with respect to the scope of the prosecution of the Application. Originally-filed independent claim 1 included the limitation "an elongate member" while originally-filed dependent claim 2 defined the "elongate member" as a "needle." (See, App. filed Dec. 19, 2001, claims 1 and 2, Exh. A). Thus, "a needle" is not new with respect to the overall prosecution of the Application.

In view of the foregoing, Applicant respectfully submits that amendment to claim 1 requested in the May 23 Response should be entered as it does not recite a new limitation as contended by the Examiner in the October 26 Advisory Action.

II. Amendments to Claims 3 and 4 Should be Entered

Applicants respectfully disagree with the Examiner's refusal to enter the amendments to claims 3 and 4 for at least the following reasons. Originally-filed claims 3 and 4 depended on claim 2. (See, App. filed Dec. 19, 2001, claims 3, 4, Exh. A) In Response to the non-final Office Action dated January 24, 2006, Applicant canceled dependent claim 2 (which depended on independent claim 1) and incorporated its limitation into independent claim 1. (See, January 24 Response, Exh. C). Applicant, however, inadvertently neglected to amend claims 3 and 4 to depend on the amended claim 1. (See, January 24 Response, Exh. C). In the final Office Action

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[1] Applicant also inadvertently submitted an incorrect status identifier for claim 1, identifying it as "previously

dated May 23, 2006, the Examiner issued a rejection of claims 3 and 4 under 35 U.S.C. § 112, second paragraph, for being dependent on a canceled claim. (See, May 23 Office Action, Exh. D). Therefore, in order to perfect claims 3 and 4 in anticipation for appeal, Applicant amended claims 3 and 4 to depend on claim 1, thus curing any deficiency under 35 U.S.C. § 112, second paragraph. (See, May 23 Response, Exh. E).

Applicant recognizes that claims 3 and 4 should have been amended in the January 24 Response, however, Applicant does not believe such an inadvertent error is an appropriate basis to refuse to enter the amendments. In view of the foregoing, Applicant respectfully submits that the amendment to claims 3 and 4 requested in the May 23 Response should be entered as it does not recite a new limitation and only perfects the claims for purposes of appeal.

CONCLUSION AND RELIEF

In view of the foregoing, Applicant respectfully requests entry of the amendments in the May 23 Response for purposes of appeal.

Respectfully submitted,

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Dated: November 20, 2006

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CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Virginia, VA 22313-1450, on November 20, 2006.

Si Vuong November 20, 2006

presented" although it was "currently amended." (See January 24 Response, Exh. C).

EXHIBIT A

Docket No.: 5618P2977
Express Mail No.: EL651846428US

UNITED STATES PATENT APPLICATION

FOR

METHOD AND APPARATUS FOR DETERMINING INJECTION DEPTH AND TISSUE TYPE

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Exhibit A

METHOD AND APPARATUS FOR DETERMINING INJECTION DEPTH AND TISSUE TYPE

FIELD OF THE INVENTION

This invention relates generally to injection devices, and more particularly to injection devices guided by heat dissipation characteristics of the body tissue through which the device is being inserted.

BACKGROUND

It is increasingly important that a physician or surgeon delivering substances, such as drugs, is able to efficiently and accurately locate the desired target tissue for effective delivery of the substance. This is particularly true when the concentration of the substance required at the target site cannot be safely or effectively achieved by introduction of the substance to a location remote from the target site. Currently, it is difficult to determine injection depth and/or tissue type without visually guiding the needle of an injection device or having some other indication of the needle location within a patient's body.

For example, fluoroscopy can be used to guide the injection device, but fluoroscopy lacks the resolution and sensitivity needed to accurately guide the injection device into the desired tissue location. Alternatively, electrocardiograph signals have been used when delivering substances to ventricular tissues of the heart, but this technique cannot be used throughout the entire body. In

addition, the use of imaging systems (e.g., ultrasonic, magnetic resonance, and optical) to view the injection device and surrounding tissue has been proposed, but the barriers to usage of such systems are large (e.g., including large capital investment, large space requirements, and ownership of intellectual property by others).

SUMMARY

A method and apparatus are disclosed for determining injection depth and/or tissue type based on the heat dissipation characteristics of body tissue. In various embodiments, an elongate member such as a needle has at least one thermally conductive heating element mounted thereon. The heating element comprises material whose electrical resistance changes in response to a change in temperature. In addition, the apparatus includes an anemometry circuitry interface electrically coupled to the heating element so that the anemometry circuitry can measure the heat dissipation characteristics of the tissue environment in which the heating element is disposed.

DESCRIPTION OF THE DRAWINGS

Various embodiments are illustrated by way of example and not by way of limitation in the figures of the accompanying drawings in which like references indicate similar elements. It should be noted that references to "an", "one", or "various" embodiments in this disclosure are not necessarily to the same embodiment, and such references mean at least one.

Figure 1 is an embodiment of a heating element coupled to a needle.

Figure 2 is an electrical schematic of anemometry circuitry according to an embodiment.

Figure 3 shows the needle structure of **Figure 1** disposed within a blood stream.

Figure 4 shows the embodiment of **Figure 3** disposed partially in a vessel wall and partly in the blood stream.

Figure 5 shows the device of **Figure 4** disposed almost entirely within the vessel wall.

Figure 6 is a graph which shows the voltage output of an embodiment as it varies over time during the insertion shown in **Figures 3-5**.

Figure 7 shows an embodiment having multiple heating elements disposed on a needle such that one sensor is within the vessel wall and one sensor is disposed within the blood stream.

DETAILED DESCRIPTION

The various embodiments described herein use heat dissipation characteristics of tissue to determine injection depth and/or tissue type. In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the various embodiments. It will be apparent, however, to one skilled in the art that the various embodiments may be practiced without some of these specific details. The following description and the accompanying drawings provide examples for the purposes of illustration only. However, these examples should not be construed in a limiting sense as they are merely intended to provide exemplary embodiments, rather than to provide an exhaustive list of all possible implementations.

Referring now to **Figure 1**, device 10 is shown which comprises cylindrical needle 12 having a lumen therethrough

with opening 14 at a distal end to access a desired area within the body. Among other functions, needle 12 can be used to deliver a substance, extract a substance, or otherwise used to puncture tissue. Examples of substances that may be delivered include drugs, pharmaceutical agents, fluids, proteins, polypeptides, gene therapy material, cell therapy material, and deoxyribonucleic acid ("DNA").

The dimensions of needle 12 will vary depending on the application. For instance, needle 12 can be designed for use with an intracardiac catheter to access a patient's atria or ventricles of the heart via a patient's vascular system, for use with an intravascular catheter to access a patient's vascular system, for percutaneous use (e.g., puncturing the skin), and for generally accessing blood-filled cavities and vessels (e.g., blood volumes).

Specifically, if needle 12 is to be used with an intracardiac catheter, the outer diameter of needle 12 is preferably between 0.065 inches (16 gage) and 0.013 inches (29 gage). In this regard, the gage sizes of hypodermic needle stock are relatively standard in the industry and refer to the outer diameter of the needle. The inner diameter will vary depending on the wall type. For intravascular catheter use, needle 12 will preferably have an outer diameter between 0.032 inches (21 gage) and 0.010 inches (31 gage). For percutaneous use, needle 12 can be any size suitable for a particular insertion location and the type of material to be injected or withdrawn. However, the most useful size range of needle 12 for percutaneous use would have an outer diameter between 0.134 inches (10 gage) and 0.009 inches (32 gage). Despite the given size ranges for each application, it is contemplated that sizes outside of the given ranges can be used.

In addition, device 10 includes heating element 16

coupled to an exterior portion of needle 12. Heating element 16 will have approximately the same diameter size constraints as needle 12 listed above for each application. This is due to the fact that a heating element which has an outer diameter substantially larger than the outer diameter of the needle could create problems when inserting and extracting device 10. Regarding the length of heating element 16, it is preferred that the length be between 0.010 inches and 0.400 inches. However, lengths outside of this range could also be used.

In various embodiments, heating element 16 comprises material whose electrical resistance changes in response to a change in temperature. Specifically, heating element 16 is constructed with a controlled temperature/resistance relationship. In various embodiments, heating element 16 is constructed of tungsten or platinum wire or a thin metallic film. These materials have a resistance which increases as the temperature increases. However, heating element 16 may be constructed of other materials such as those used in thermistors and other devices that exhibit changes in electrical resistance in response to a change in temperature.

Device 10 additionally includes first electrically conductive lead 20 electrically coupled to a first end of heating element 16 and second electrically conductive lead 22 electrically coupled to a second end of heating element 16 to serve as an interface with anemometry circuitry. In other embodiments, an alternative anemometry circuitry interface could be used. Although anemometry circuits are generally used to measure flow rates of fluids, the various embodiments disclosed herein use anemometry circuitry to measure heat dissipation (e.g., flow of thermal energy) from heating element 16.

Although the embodiment shown utilizes cylindrical needle 12 to mount heating element 16, other embodiments contemplate other elongate members (that may be non-cylindrical) so long as they are suitable for insertion into a body. For example, the elongate member could be a thin rod (with or without opening 14 and with or without a sharpened distal end). Furthermore, opening 14, if present, could be disposed more proximally on needle 12, which would allow for heating element 16 to be disposed distal to opening 14. Such a configuration would advantageously provide for heat dissipation measurement in situations in which tissue just distal of the desired injection depth provides a more reliable or larger signal change/reading.

Figure 1 depicts heating element 16 as a wire. The wire should be large enough to conduct a sufficient amount of current but small enough to be effectively mounted on needle 12. It is worth noting that in various embodiments, heating element 16 can comprise at least one of a wire, a film, and a thermistor material.

In one embodiment, heating element 16 has a length that is approximately equal to or less than the known thickness of a targeted tissue (accounting for the tissue penetration angle of device 10) whose heat dissipation characteristics are to be measured by device 10. Embodiments which include this feature are able to more discretely measure heat dissipation characteristics and detect differences in such characteristics than embodiments with heating elements 16 which are longer and, therefore, have no penetration depth at which heating element 16 is surrounded by only the targeted tissue.

In the embodiment shown in **Figure 1**, heating element 16 is shown having a coil portion 18 wrapped around needle 12 with covering 24 disposed over coil portion 18. Covering 24

is adhered to needle 12 or formed as an integral part of needle 12. Covering 24 protects heating element 16 and provides for a smooth transition with the surface of needle 12 to make insertion of needle 12 into tissue easier and less traumatic.

Covering 24 can be made of a non-conductive material to insulate the patient from electrical current flowing through coil portion 18. Moreover, the wire that forms coil portion 18 may also be coated with an electrical insulator. Thus, either or both methods of providing electrical insulation described herein may be used.

Figure 1 shows heating element 16 as a coiled wire. Other wire configurations are also suitable. For example, heating element 16 can be formed by placing the center of the wire near the distal end of heating element 16 and winding each end 20 and 22 in opposite directions around needle 12 towards the proximal end of needle 12. Alternatively, the wire may be wound in a zigzag pattern, proximally and distally, back and forth in a desired area. Alternatively, heating element 16 can be formed by mounting the wire within a groove or a plurality of grooves formed within the surface of needle 12.

In addition to wire configurations, heating element 16 can be formed by sputtering a thin film of metal over a masked insulator (masked to lay down the desired heating element metal configuration), removing the mask, attaching the conductors, and coating the remaining metal connections with an insulator (e.g., a dielectric material). Moreover, a photo-etching process, similar to that used in the microelectronics industry, could be used to remove metal from needle 12 in the desired configuration.

Heating element 16 can be mounted on needle 12 such that distance 26 (from the distal end of opening 14 to the

proximal end of heating element 16) is substantially equivalent to a desired injection depth. Heating element 16 may be enclosed or mounted on or in a suitable assembly, syringe, or catheter to aid in the insertion, advancement, orientation, and delivery of device 10 to the desired position within the body prior to injection.

In addition, the proximal end of device 10 may be provided with suitable electrical connections to external circuitry and/or instrumentation (not shown) as well as fluid connections to force the injectant through device 10. Common catheter assemblies provide such connections.

In various embodiments, needle 12 can be comprised of material which is not electrically conductive (e.g., ceramic) or material which is electrically conductive (e.g., stainless steel). It is worth noting that ceramic needles advantageously increase response time and sensitivity of heating element 16 due to the reduced thermal mass and thermal conductivity of ceramic. However, electrically conductive materials have electrical connection advantages, which can simplify device design. For instance, in embodiments in which a portion of needle 12 is electrically conductive, heating element 16 can be connected to anemometry circuitry by (i) first electrically conductive lead 20 electrically coupled to a first end of heating element 16 and (ii) a conductive portion of needle 12 coupled to a second end of heating element 16.

If a high thermal mass needle (e.g., stainless steel) is used, a thermal insulator can be disposed between heating element 16 and needle 12 to minimize any reduction in response time and sensitivity of heating element 16 caused by needle 12.

Regardless of the construction and materials used to construct heating element 16, device 10 can have more than

just a single heating element 16, as shown in **Figure 1**. For instance, if a plurality of heating elements 16 are mounted on needle 12 and operated separately and/or in groups, multiple penetration depths/tissue types can be controlled/identified. In addition, a single penetration depth can be more effectively controlled with an embodiment which utilizes a plurality of heating elements 16.

Turning now to **Figure 2**, an embodiment of anemometry circuitry is shown. In the embodiment shown, the anemometry circuitry is configured to measure the heat dissipation characteristics of an environment in which heating element 16 is disposed. The anemometry circuitry is electrically coupled to heating element 16 shown in **Figure 1**. Specifically, a first end of heating element 16 is electrically coupled to first junction 42 of bridge circuit 28, and a second end of heating element 16 is electrically coupled to node 41 of bridge circuit 28.

Figure 2 is a simplified representation of a temperature controlled hot wire or hot film anemometer system. Although there are many ways to operate an anemometer system (e.g., constant current or constant voltage), temperature controlled is preferred because the various embodiments are intended to be used within the body. Control over the temperature of heating element 16 can advantageously avoid tissue damage caused by temperature. In addition, signal level changes in response to the heat dissipation characteristics of the environment in which heating element 16 is disposed will be maximized.

The anemometry circuitry shown in **Figure 2** includes balancing bridge circuit 28, controlled amplifier 30, and signal amplifier 32. Although other designs and configurations for the circuitry could be used, this simplified representation is included for ease of

discussion. Bridge circuit 28 is comprised of heating element 16, a system controlled variable resistor 34 and two fixed resistors 36 and 38. Heating element 16 acts as a resistor within bridge circuit 28.

Bottom node 41 of bridge 28 is connected to ground (e.g. 0 volts). Thus, when a voltage is applied at top node 40 of bridge 28, current will flow through heating element 16, causing a dissipation of power. Due to the material and construction of heating element 16, the dissipated power is dissipated as heat. The heat will raise the temperature of heating element 16 such that the temperature change will cause a change in the resistance of heating element 16.

For the sake of simplicity, it is assumed that fixed resistors 36 and 38 have the same resistance value. Although this is not required, this assumption makes explanation of the anemometry circuitry easier to understand. As heating element 16 increases in temperature, the resistance of heating element 16 also increases, causing the voltage at first junction 42 (between heating element 16 and resistor 36) to increase.

Thus, if variable resistor 34 has a resistance value adjusted by the circuitry to be equal to that of heating element 16, then the voltage at second junction 44 (between fixed resistor 38 and variable resistor 34) will be the same as at first junction 42. When the voltages are equivalent, bridge circuit 28 is understood to be "balanced". Thus, once variable resistor 34 has been adjusted to have a resistance value equal to that of heating element 16, any changes to the resistance of heating element 16 (e.g., caused by changes in temperature) will cause the voltage at junction 42 to change in the direction of and roughly in proportion to the temperature change of heating element 16. Thus, the voltage at first junction 42 would be either

higher or lower than the voltage at second junction 44.

Amplifier 30 is electrically coupled to bridge circuit 28 to sense the difference in voltage drop across heating element 16 and variable resistor 34 caused by the difference between the resistance of heating element 16 and the resistance of variable resistor 34. Amplifier 30 receives power from positive Vsupply and is also coupled to ground. Amplifier 30 compares the voltages of positive input 46 and negative input 48. If positive input 46 is a higher voltage than negative input 48, the positive difference between input 46 and input 48 is amplified and output through line 50.

It is worth noting that no voltage higher than positive Vsupply will be seen at output 50. If negative input 48 is equal to or higher than positive input 46, then the voltage present at output 50 will be a low positive value (e.g., too low to cause significant heating of heating element 16). Amplifier 30 is able to compare the input voltages since positive input 46 is connected to second junction 44, and negative input 48 is connected to first junction 42. Output 50 of amplifier 30 is connected to top node 40 of bridge circuit 28.

Focusing now on the interaction between amplifier 30 and bridge circuit 28, it is assumed that bridge circuit 28 is initially in a balanced condition. Thus, the voltage applied to top node 40 of bridge circuit 28 by output 50 of amplifier 30 is low, and heating element 16 is not being heated. Also, the resistance of heating element 16 is equal to that of variable resistor 34.

If the anemometry circuitry system raises the resistance of variable resistor 34, the voltage at junction 44 will exceed the voltage at junction 42. This, in turn, creates a positive voltage difference between positive input

46 and negative input 48. This positive voltage difference causes output 50 to dramatically rise in voltage.

Output 50 is applied to top node 40 of bridge circuit 28, raising the current through heating element 16, which causes the power (e.g., heat) dissipated by heating element 16 to increase dramatically. The increase in heat dissipated by heating element 16 results in an increase in the temperature of heating element 16.

When the temperature of heating element 16 nearly reaches the temperature at which the resistance of heating element 16 is the same as that of variable resistor 34, the voltages at junctions 42 and 44 will be very close to equal. In addition, output 50 applied to top node 40 of bridge circuit 28 will begin to drop until an equilibrium is reached. Upon reaching this equilibrium, heating element 16 will be heated to a temperature that correlates to a resistance that is very close to that of variable resistor 34. With high amplification factors in amplifier 30, this resistance difference can be made to be negligible.

Since the resistance/temperature relationship of heating element 16 is known and heating element 16 now has the same resistance as variable resistor 34, the temperature of heating element 16 is also known. Thus, this interaction allows the temperature of heating element 16 to be set by adjusting the value of variable resistor 34 so long as positive Vsupply can supply enough voltage/current to top node 40 of bridge circuit 28 to sufficiently heat heating element 16 to the desired temperature. It is worth noting that the desired temperature is above ambient temperature of heating element 16 and that output 50 is at some intermediate voltage value between the maximum and minimum values for which amplifier 30 is configured when heating element 16 is heated above the ambient temperature.

Thus, output 50 is directly related to the heat transfer environment of heating element 16. If that environment carries heat away from heating element 16 rapidly, then output 50 will be a higher value than if that environment carries heat away more slowly.

It is expected that these changes in output 50 may be small. Thus, signal amplifier 32 is employed to increase the size of the change to a level suitable for an associated instrument (not shown) to sample, process, and display the measurements in a suitable manner. Signal amplifier 32 operates similarly to controlled amplifier 30. However, signal amplifier 32 is supplied with negative Vsupply, instead of power supply ground. Thus, output 56 may vary between the values of positive Vsupply and negative Vsupply in response to the voltage difference of inputs 52 and 54.

If positive input 52 is a higher voltage than negative input 54, then the positive difference between the two inputs is amplified, and the amplified voltage is presented at output 56. If positive input 52 is a lower voltage than negative input 54, then the negative difference between the two inputs is amplified, and the amplified negative voltage is presented at output 56. It is worth noting that the amplification factor for negative and positive differences is the same.

Negative input 54 is connected to wiper 58 of system controlled potentiometer 60. Potentiometer 60 is also connected to positive Vsupply and power supply ground such that, as wiper 58 is adjusted, the voltage at wiper 58 will vary between zero and the voltage of positive Vsupply.

Assuming that heating element 16 is maintained at a higher than ambient temperature, amplifier 32 behaves in the following manner. Since voltage output 50 is connected to positive input 52 of amplifier 32, input 52 is at some

intermediate positive voltage level. The anemometry circuitry may then adjust wiper 58 such that negative input 54 is at or nearly at the same voltage as input 52. Thus, voltage output 56 of amplifier 32 will be approximately zero.

However, if heating element 16 is moved to an environment that transfers heat more rapidly, positive input 52 (from output 50) will exceed negative input 54 (from wiper 58), and output 56 of amplifier 32 will increase a multiple of the actual increase seen at input 52 due to an amplification factor of amplifier 32. If heating element 16 is moved to an environment that transfers heat less rapidly, positive input 52 will be less than negative input 54, and output 56 of amplifier 32 will have a negative value which is a multiple of the actual decrease seen at input 52.

Although anemometry circuitry is generally used to measure the flow velocity of fluid or gas, or, where the dimensions of the flow conduit are known or constant, to calculate flow rates, various embodiments described herein use the detected differences in the heat dissipation characteristics of different body tissues to determine injection depth and/or tissue type. It is worth noting that the embodiments disclosed herein should not be limited to measuring the heat dissipation characteristics of tissues since there are other materials within the body which are not generally considered tissues but will still have measurable heat dissipation characteristics. For instance, spinal fluid and amniotic fluid are not considered tissues but could have their respective heat dissipation characteristics measured to determine injection depth or material type.

Focusing now on exemplary heat dissipation characteristics of different materials, atheroma is a

degenerative accumulation of lipid-containing plaque on the innermost layer of a wall of an artery. For heat dissipation purposes, atheroma is generally a waxy substance with no blood flow. If device 10 were inserted into a layer of atheroma, heating element 16 would only dissipate a negligible amount of heat.

Similarly, fat tissue does not have much blood flow, and therefore, heating element 16 inserted into fat tissue would experience a low heat dissipation rate. However, the same heating element 16 inserted into muscle tissue, which has substantial blood flow, would experience a high heat dissipation rate, and if heating element 16 were inserted into a moving blood stream, the heat dissipation rate experienced by heating element 16 would be extremely high.

Figures 3-6 demonstrate how device 10 with a single heating element 16 can be used to control the depth of penetration of needle 12 into the wall of a coronary artery to desired penetration depth 26. It is assumed that device 10 is inside a suitable catheter (not shown) at the desired location, that the catheter is a relatively good thermal insulator, that heating element 16 is being driven at a temperature above blood temperature, and that the anemometry circuitry which drives heating element 16 is connected to heating element 16 and properly configured.

Figure 6 shows a graph of voltage output 56 of amplifier 32 versus time. Before T_1, heating element 16 is inside the catheter (not shown). Since the catheter is assumed to be a relatively good thermal insulator, the drive voltage or current required to keep heating element 16 at a stable temperature is low. Thus, output 56 of amplifier 32 is very negative. At time T_1, device 10 is rapidly moved out of the catheter and into blood stream 62 of the artery (**Figure 3**).

Blood stream 62 carries away heat at an extremely high rate, which cools heating element 16 mounted on device 10 rapidly. Thus, output 56 rises rapidly to a maximum value and remains at the maximum value until T_2, when heating element 16 has almost reached the set temperature (or resistance) again. At T_3, bridge circuit 28 reaches equilibrium with the new heat dissipation environment of blood stream 62. The line segment between T_3 and T_4 represents the new equilibrium level. This line segment is shown as a straight line for simplicity, but in reality, this line segment would have oscillations due to changes in the velocity of blood stream 62 relative to heating element 16 during the cardiac cycle.

The line segment between T_4 and T_5 represents the smooth continuous insertion of heating element 16 into artery wall 64 (**Figure 4**). Since artery wall 64 will be composed of atheroma, muscle tissue, connective tissue, and other surrounding tissues with low heat flow characteristics, artery wall 64 will be a better thermal insulator than blood stream 62. Thus, output 56 will change in a negative direction until heating element 16 is completely within artery wall 64 at T_5. **Figure 5** shows device 10 inserted into artery wall 64 to desired penetration depth 26.

As discussed above, the line segment between T_4 and T_5 is shown as a straight line for simplicity, but in fact, the line segment will have the same cardiac cycle bumps as the line segment between T_3 and T_4. However, as more of heating element 16 is inserted into artery wall 64, the amplitude of these cardiac bumps will decrease until heating element 16 is no longer in blood stream 62.

One drawback of the single heating element design is that if needle 12 were inserted further into artery wall 64,

there would be little change in output 56 to alert the user of the change in position. However, if second heating element 17 were mounted just proximal to first heating element 16 (**Figure 7**), then desired penetration depth 26 could be more easily determined. Assuming heating elements 16 and 17 are constructed in the same manner, desired penetration depth 26 would be located when the greatest difference in outputs 56 of each of the respective heating elements was observed.

If needle 12 were further inserted into artery wall 64, output 56 of heating element 17 would decline toward the value of output 56 for heating element 16. Conversely, if needle 12 were withdrawn from artery wall 64, then output 56 of heating element 16 would increase toward the output 56 of heating element 17. Thus, multiple heating elements allow for monitoring the depth of penetration of needle 12 within relatively close limits relative to any tissue interface where the two interfacing tissues have sufficient difference in heat dissipation characteristics and thickness relative to the length of heating elements 16 and 17 to be detectable.

As shown in **Figure 7**, multiple heating elements can be constructed within a single heating element assembly. For example, in the embodiment shown, heating element 16 and heating element 17 are both disposed in covering 24. In addition, only three electrical leads are required since each heating element has a separate bridge circuit 28 (not shown) connecting the heating element to ground (node 41 in **Figure 2**). Thus, heating element 16 and heating element 17 share a lead to ground. In embodiments which use needle 12 as a conductive lead, needle 12 can be used as the ground connection for all heating elements.

The embodiments disclosed herein can be operated by

much more complex and sophisticated circuitry and instrumentation to filter, process, and detect the differences in the heat dissipation characteristics of different tissue types. For example, the temperature of heating element 16 could be stepped in increments small enough to avoid saturating amplifier 30 toward or away from body temperature, using the rate of equilibrium establishment to differentiate tissue types or boundaries in a more rapid manner.

It is to be understood that even though numerous characteristics and advantages of various embodiments have been set forth in the foregoing description together with details of structure and function of the various embodiments, this disclosure is illustrative only. Changes may be made in detail, especially matters of structure and management of parts, without departing from the scope of the various embodiments as expressed by the broad general meaning of the terms of the appended claims.

CLAIMS

I claim:

1. An apparatus comprising:

an elongate member having dimensions suitable for insertion into a body;

at least one thermally conductive heating element coupled to a portion of the elongate member, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an anemometry circuitry interface electrically coupled to the heating element.

2. The apparatus of Claim 1, wherein the elongate member comprises a needle.

3. The apparatus of Claim 2, wherein the needle has an outer diameter between 0.009 inches and 0.134 inches.

4. The apparatus of Claim 2, wherein the needle comprises a material of at least one of stainless steel and ceramic.

5. The apparatus of Claim 1, wherein the elongate member is a rod.

6. The apparatus of Claim 1, wherein the heating element comprises at least one of a wire, a film, and a thermistor material.

7. The apparatus of Claim 1, wherein the heating element has a length which is approximately equal to or less than a known tissue thickness.

8. The apparatus of Claim 7, wherein the length of the heating element is between 0.010 inches and 0.400 inches.

9. The apparatus of Claim 1, wherein the anemometry circuitry interface comprises:

a first electrically conductive lead electrically coupled to a first end of the heating element; and

a second electrically conductive lead electrically coupled to a second end of the heating element.

10. The apparatus of Claim 1, wherein a portion of the elongate member comprises an electrically conductive material and wherein the anemometry circuitry interface comprises:

an electrically conductive lead electrically coupled to a first end of the heating element, and

the elongate member electrically coupled to a second end of the heating element.

11. An apparatus comprising:

a needle having dimensions suitable for insertion into a body;

at least one thermally conductive heating element coupled to a portion of the needle, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

anemometry circuitry electrically coupled to the heating element.

12. The apparatus of Claim 11, wherein the needle has an outer diameter between 0.009 inches and 0.134 inches.

13. The apparatus of Claim 11, wherein the needle comprises a material of at least one of stainless steel and ceramic.

14. The apparatus of Claim 11, wherein the heating element comprises at least one of a wire, a film, and a thermistor material.

15. The apparatus of Claim 11, wherein the heating element has a length which is approximately equal to or less than a known tissue thickness.

16. The apparatus of Claim 15, wherein the length of the heating element is between 0.010 inches and 0.400 inches.

17. The apparatus of Claim 11, wherein the anemometry circuitry is electrically coupled to a first end of the heating element by a first electrically conductive lead and is electrically coupled to a second end of the heating element by a second electrically conductive lead.

18. The apparatus of Claim 11, wherein a portion of the elongate member comprises an electrically conductive material and wherein the anemometry circuitry is electrically coupled to a first end of the heating element by an electrically conductive lead and is electrically coupled to a second end of the heating element by the elongate member.

19. The apparatus of Claim 11, wherein the anemometry circuitry comprises:

a circuit having the heating element and a variable resistor as resistive circuit elements; and

an amplifier electrically coupled to the circuit

to sense the difference in voltage drop across the heating element and the variable resistor caused by the difference between a first resistance of the heating element and a resistance of the variable resistor,

to amplify the voltage difference, and

to input the amplified voltage difference back to the circuit to cause a modification of a temperature of the heating element such that the heating element assumes a second resistance.

20. The apparatus of Claim 19, wherein a plurality of heating elements are coupled along a length of the elongate member, and further comprising:

anemometry circuitry separately coupled to each of the heating elements such that the heat dissipation characteristics measured by the plurality of anemometry circuits can be used to determine at least one of injection depth and tissue type.

21. A method comprising:

introducing a heat dissipation measurement device into a body comprising tissue; and

determining at least one of injection depth and tissue type based on measured heat dissipation characteristics of the tissue.

22. The method of Claim 21, further comprising identifying a location of at least one tissue/tissue interface.

23. The method of Claim 22, wherein the heat dissipation measurement device comprises at least two thermally conductive heating elements and wherein identifying comprises:

inserting the heat dissipation measurement device into a first tissue such that a first heating element is disposed within the first tissue and positioned to measure heat dissipation characteristics of the first tissue; and

moving the heat dissipation measurement device further into the body such that

the first heating element is disposed in a second tissue and positioned to measure heat dissipation characteristics of the second tissue, and

a second heating element is disposed in the first tissue and positioned to measure heat dissipation characteristics of the first tissue.

24. The method of Claim 23, wherein the first tissue is one of a vessel wall and a blood volume and the second tissue is the other of the vessel wall and the blood volume.

25. The method of Claim 23, wherein the first tissue is one of a cardiac muscle and a blood volume and the second tissue is the other of the cardiac muscle and the blood volume.

ABSTRACT

A method and apparatus are disclosed for determining injection depth and/or tissue type based on the heat dissipation characteristics of body tissue.

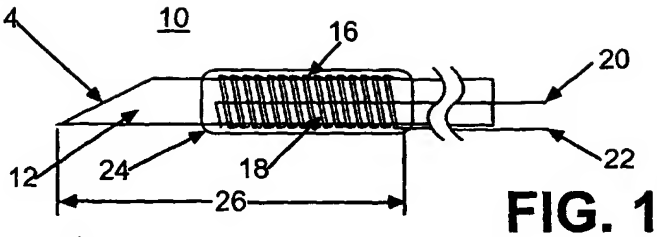

FIG. 1

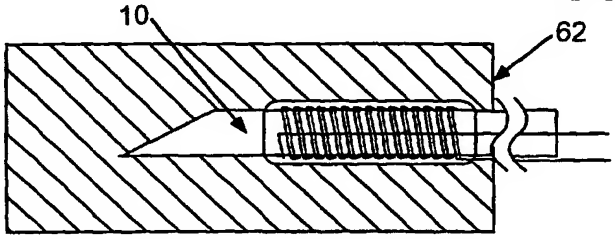

FIG. 3

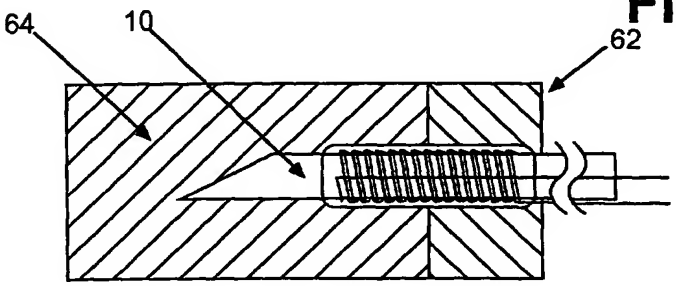

FIG. 4

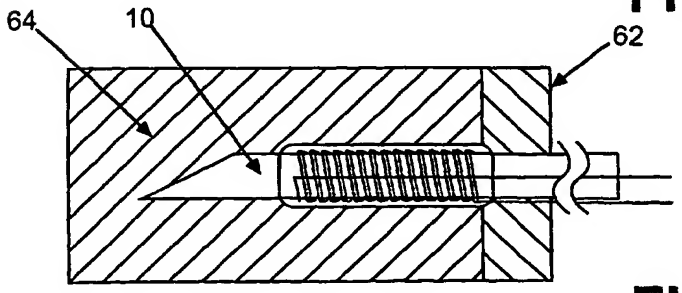

FIG. 5

FIG. 6

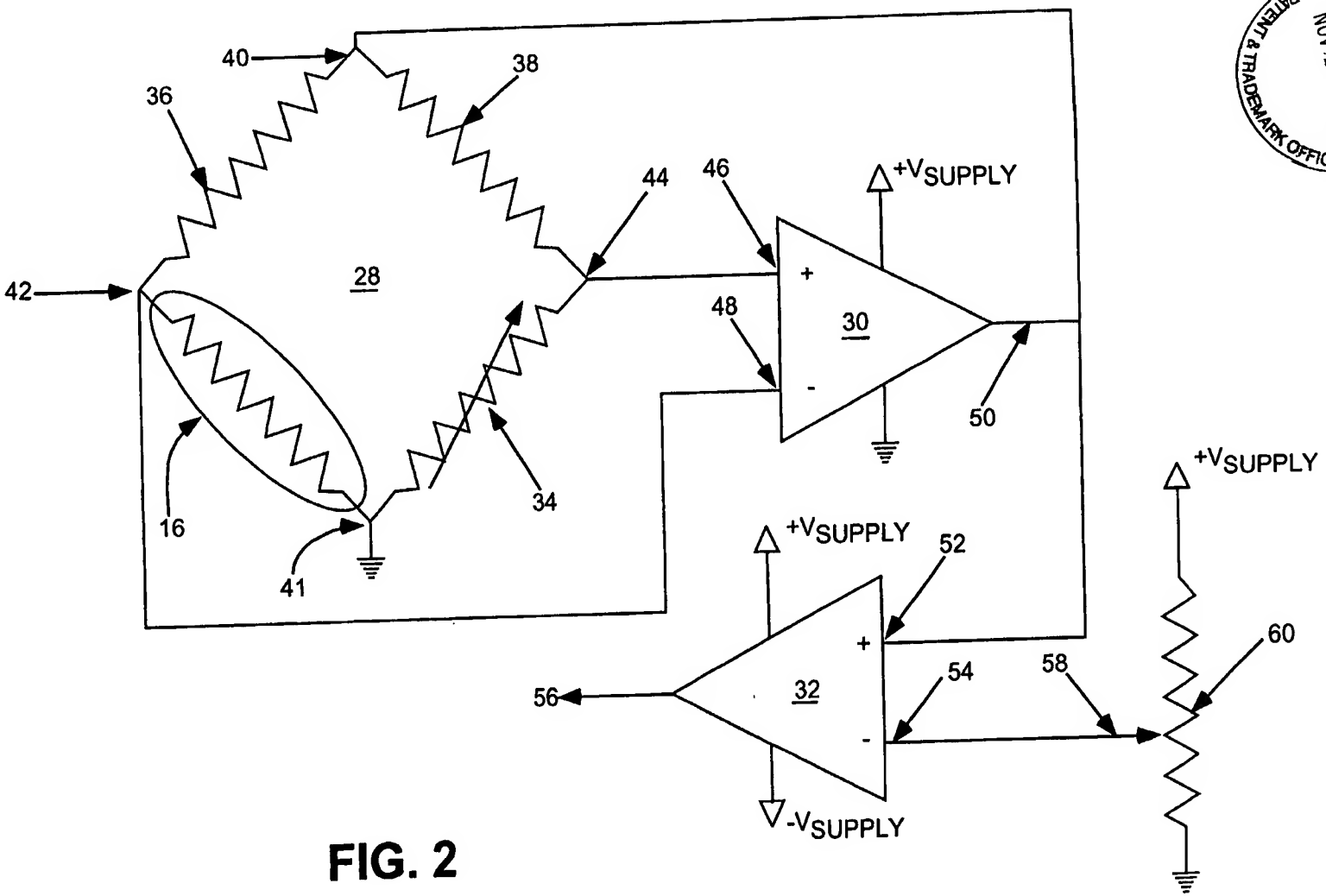

FIG. 2

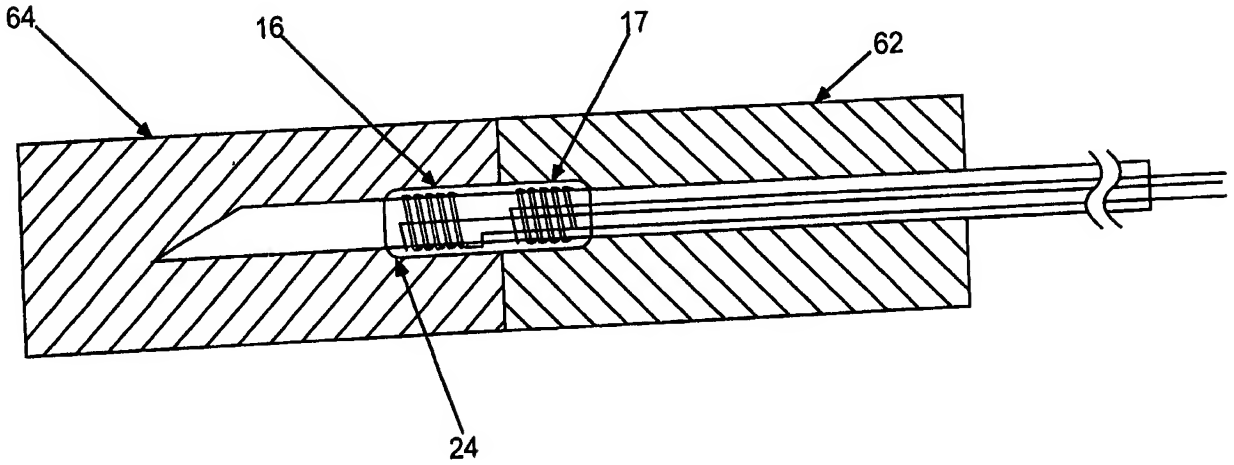

FIG. 7

EXHIBIT B

P-

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,877	12/19/2001	William Earl Webler	5618P2977	1005

8791 7590 01/24/2006

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Exhibit B

Office Action Summary	Application No.	Applicant(s)	
	10/027,877	WEBLER, WILLIAM EARL	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/05 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 – 3, 5 – 9, 11, 12, 14 – 20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al.

In regards to claims 1 – 3, 5 – 9, 11, 12, 14 – 20 and 26, Tay et al. discloses an elongate member as a needle, in that Tay et al. discloses the probe as a hollow elongated member (Col. 20, lines 12 – 18), or rod insertable into a body; a thermally conductive heating element coupled to the distal portion of the elongate member, the heating element comprising a wire whose electrical resistance changes in response to a change in temperature (Col. 20, lines 45 – 49). The needle includes a distal opening, and a lumen (148; Figure 21) extending from a proximal end to the distal opening (Col. 16, lines 12 – 15) in communication with the distal opening capable of allowing a

substance to be delivered through the lumen. The distal end of the needle is capable of puncturing skin (Col. 15, line 65 – Col. 16, line 1). Tay et al. discloses anemometry circuitry and comparing a first resistance and a second resistance of the at least one heating element to indicate a change of conditions related to a distance of penetration of the heating element (Col. 20, lines 48 – 54). Tay et al. discloses an outer diameter between 0.009 inches and 0.134 inches (Col. 19, line 56 – Col. 20, line 18). The heating element is less than the thickness of the tissue in which it is inserted. In order to operate the device as disclosed by Tay et al. must include a first and second lead coupled to the at least one heating element. However, Tay et al. fails to disclose the anemometry circuitry comprising the heating element and a variable resistor as resistive circuit element. Nor does Tay et al. disclose an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance. Lull et al. teaches a circuit for use in a constant temperature anemometer (Col. 17, lines 10 - 15) comprising a balanced circuit (Col. 11, lines 40 – 46) having the heating element (R_1, R_2) and a variable resistor (Col. 7, lines 49 - 52) as resistive circuit element and an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance (Col. 7, line 25 – Col. 8, line 22). Lull et al. discloses anemometry circuitry separately coupled to each of the heating elements. It would have been obvious to one having ordinary skill in the art to modify the circuitry as disclosed by Tay et al. to include an interface to the balanced circuit as disclosed by Lull et al. in order to compare variations in the resistance of the heating elements (Col. 17, lines 10 – 15). Tay et al. fails to disclose the heating element being between 0.010 inches and 0.400 inches. However, a

change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),

cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

4. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 2 and 11 above, and further in view of U.S. Patent No. 3,470,604 to Zenick.

In reference to claims 4 and 13, Tay et al. in view of Lull et al. discloses a needle, but fails to disclose the needle being formed of stainless steel. However, stainless steel is well known in the medical industry for its strength, durability, ease of sterilization etc. Zenick discloses a hypodermic needle that is formed of stainless steel (Col. 1, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the needle as disclosed by Tay et al. in view of Lull et al. out of stainless steel as taught by Zenick in order to have a sturdy, durably and easily sterilized hypodermic needle for insertion into a patient.

5. Claims 10 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 5,873,835 to Hastings et al.

6. In regards to claims 10 and 18, Tay et al. in view of Lull et al. fails to disclose the forming the elongate member of an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member. Hastings et al. teaches a portion of the elongate member being electrically conductive and the anemometry circuitry interface comprising an electrically conductive lead electrically coupled to a first end of the heating element, and the elongate member electrically

coupled to a second end of the heating element (Col. 11, lines 33 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the elongate member as disclosed by Tay et al. in view of Lull et al. to be an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member as taught by Hastings et al. in order to reduce the resistance of the electrical connections to the heating element (Col. 11, lines 33 – 35).

Response to Arguments

Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive. Applicant asserts that although Tay et al. allows for the possibility of blood flowing out of the puncture in the vessel and through the insulation layer and out of hole, Tay et al. does not teach or suggest a distal opening, and a lumen extending from a proximal end to the distal opening in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening. However, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. ***In re Pearson***, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); ***In re Casey***, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); ***In re Otto***, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. ***In re Ludtke***, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may

be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. ***In re Spada***, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); ***In re King***, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); ***In re Ludtke***, 441 F.2d 664, 169 USPQ 566 (CCPA 1971). In the present case, the lumen (148; Figure 21) extending from a proximal end to the distal end (Col. 16, lines 12 – 15) in communication with the distal opening disclosed by Tay et al. is fully capable of allowing a substance to be delivered through the lumen and out of the opening. Applicant asserts that the distal end of the elongate member as disclosed by Tay et al. is not capable of puncturing skin. However the examiner disagrees. Provided enough force, a blunt object is capable of puncturing skin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

MAX F. HINDENBURG
PRIMARY PATENT EXAMINER
TECHNOLOGY CENTER 3700

EXHIBIT C

Attorney's Docket No. 005618.P2977

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

William Earl Webler

Application No. 10/027,877

Filed: December 19, 2001

For: METHOD & APPARATUS FOR DETERMINING INJECTION DEPTH & TISSUE TYPE

Examiner: Jonathan M. Foreman

Art Unit: 3736

AMENDMENT AND RESPONSE TO OFFICE ACTION

Mail Stop Amendments - No Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action dated January 24, 2006, please amend and the above-captioned application as set for below.

Amendments to the Claims are reflected in the Listing of Claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Exhibit C

AMENDMENTS

In the claims:

This Listing of Claims replaces all prior versions, and listings, of the claims in this application.

Listing of Claims:

AMENDMENTS TO THE CLAIMS

1. (Previously Presented) An apparatus comprising:

~~an elongated member~~ a needle having dimensions suitable for insertion into a body, a distal portion suitable for insertion into tissue, a distal opening, and a lumen extending from a proximal end to the distal opening and in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening;

a thermally conductive heating element coupled to the distal portion of the elongate member, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an interface to a balanced circuit having the heating element and a variable resistor as resistive circuit elements, wherein the balanced circuit measures a first differential resistance between the heating element and the variable resistor in response to a first condition and a second differential resistance in response to a second condition in circuitry to indicate a change of conditions related to a distance of penetration of the thermally conductive heating element into a tissue.

2. Canceled.

3. (Original) The apparatus of Claim 2, wherein the needle has an outer diameter between 0.009 inches and 0.134 inches.

4. (Original) The apparatus of Claim 2, wherein the needle comprises a material of at least one of stainless steel and ceramic.

5. (Original) The apparatus of Claim 1, wherein the elongate member is a rod.

6. (Original) The apparatus of Claim 1, wherein the heating element comprises at least one of a wire, a film, and a thermistor material.

7. (Previously Presented) The apparatus of Claim 1, wherein the heating element has a length which is approximately equal to or less than the thickness of a tissue in to which at least a portion of the elongate member is to be inserted.

8. (Original) The apparatus of Claim 7, wherein the length of the heating element is between 0.010 inches and 0.400 inches.

9. (Previously Presented) The apparatus of Claim 1, wherein the interface is an anemometry circuitry interface comprising:

a first electrically conductive lead electrically coupled to a first end of the heating element; and

a second electrically conductive lead electrically coupled to a second end of the heating element.

10. (Previously Presented) The apparatus of Claim 1, wherein a portion of the elongate member comprises an electrically conductive material and wherein the interface comprises:

an electrically conductive lead electrically coupled to a first end of the heating element, and

the elongated member electrically coupled to a second end of the heating element.

11. (Previously Presented) An apparatus comprising:

a needle having dimensions suitable for insertion into a body, and having a distal end capable of puncturing skin;

a thermally conductive heating element coupled to a portion of the needle, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an interface to electrically couple an anemometry circuitry to the heating element, wherein the circuitry comprises a balanced circuit having the heating element and a variable resistor as resistive circuit elements.

12. (Original) The apparatus of Claim 11, wherein the needle has an outer diameter between 0:009 inches and 0.134 inches.

13. (Original) The apparatus of Claim 11, wherein the needle comprises a material of at least one of stainless steel and ceramic.

14. (Previously Presented) The apparatus of Claim 11, further comprising anemometry circuitry electrically coupled to the heating element wherein the circuitry comprises a balanced circuit having a heating element and a variable resistor as resistive circuit elements, wherein the heating element comprises at least one of a wire, a film, and a thermistor material.

15. (Previously Presented) The apparatus of Claim 11, wherein the heating element has a length which is approximately equal to or less than the thickness of a tissue in to which at least a portion of the needle is to be inserted.

16. (Original) The apparatus of Claim 15, wherein the length of the heating element is between 0.010 inches and 0.400 inches.

17. (Previously Presented) The apparatus of Claim 14, wherein the anemometry circuitry is electrically coupled to a first end of the heating element by a first electrically conductive lead and is electrically coupled to a second end of the heating element by a second electrically conductive lead.

18. (Previously Presented) The apparatus of Claim 14, wherein a portion of the elongate member comprises an electrically conductive material and wherein the anemometry circuitry is electrically coupled to a first end of the heating element by an electrically conductive lead and is electrically coupled to a second end of the heating element by the elongate member.

19. (Previously Presented) The apparatus of Claim 14, wherein the anemometry circuitry comprises:

a circuit having the heating element and a variable resistor as resistive circuit elements; and

an amplifier electrically coupled to the circuit

to sense the difference in voltage drop across the heating element and the variable resistor caused by the difference between a first resistance of the heating element and a resistance of the variable resistor,

to amplify the voltage difference, and

to input the amplified voltage difference back to the circuit to cause a modification of a temperature of the heating element such that the heating element assumes a second resistance.

20. (Previously Presented) The apparatus of Claim 19, further comprising an additional heating element wherein the heating element and the additional heating element are coupled along a length of the elongate member, and further comprising:

anemometry circuitry separately coupled to each of the heating element and the additional heating element such that the heat dissipation characteristics measured by the plurality of anemometry circuits can be used to determine at least one of injection depth and tissue type.

21-25. Canceled.

26. (Previously Presented) The apparatus of Claim 11 wherein the needle has dimensions suitable for insertion into a tissue of the body and the balanced circuit is configured to measure a distance of penetration of the thermally conductive heating element into the tissue.

REMARKS

Claims 1-20 and 26 were examined. Claims 1-20 and 26 were rejected. Claim 1 is amended. Claim 2 is canceled. Claims 1, 3-20 and 26 remain in the application.

Claims 1-3, 5-9, 11, 12, 14-20 and 26 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,063,085 to Tay et al. (*Tay*) in view of U.S. Patent No. 6,539,792 to Lull et al. (*Lull*). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicant respectfully submits that a *prima facie* case of obviousness has not been established.

More particularly, none of the cited references either singly or combined provide the suggestion or motivation to modify the references. *Tay* discloses an apparatus for closing and sealing a puncture at a puncture site in a vessel located beneath the skin using radio frequency or other energy to cauterize the puncture. (col. 2, lns. 45-47) *Lull* discloses a sensor that includes a first resistor, a second resistor, a first circuit, and a second circuit wherein the first and second resistors each has a resistance that varies in response to a change in a physical property. (Abstract) According to *Lull*, the sensor can be applied in semiconductor manufacturing processes and automotive applications. (col. 17. lns. 1-5)

In contrast, independent claim 1 is directed to a needle coupled to a thermally conductive heating element, wherein the heating element is coupled to balanced circuit which measures a first differential resistance between the heating element and a variable resistor in response to a first condition and second differential resistance in response to a second condition to indicate a change of conditions related to a distance of penetration of the heating element into a tissue. Independent claim 11 is directed to a needle coupled to a thermally conductive heating element, wherein the heating element is coupled to a balanced circuit having two resistive circuit elements. According to the Application, a balanced circuit is capable of measuring heat dissipation characteristics of a tissue environment in which the heating element is disposed.

Thus, independent claims 1 and 11 contemplate an apparatus for determining injection depth and/or tissue type based on the heat dissipation characteristics of body tissue.

The nature of a problem addressed by Applicant's invention is to accurately determine injection depth of a needle in tissue other than by visual guidance means. On the other hand, the nature of the problem addressed in *Tay* is to seal puncture wounds in vessels. The nature of the problem addressed in *Lull* is to overcome a sensor's inoperability due to a circuit's inability to discern differences in flow rate of fluid due to fixed temperature coils. As such, there is no suggestion or motivation to modify the references to teach Applicant's invention. *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998) (even though the references taught every element of the claimed invention, there was no motivation to combine, rendering the rejection based on a *prima facie* case of obviousness improper). It should also be noted that neither *Tay* nor *Lull* teach a limitation of a needle having a distal portion and/or end suitable for insertion into tissue and/or capable of puncturing skin. (App., claims 1, 11) The Examiner cites *Tay* for these limitations, however, *Tay* teaches sealing wounds and not creating them, as evidenced in the specification: "[a]n apparatus for closing and sealing a vascular puncture." (col. 2, lns. 45-46) Accordingly, Applicant respectfully submits that independent claims 1 and 11 and their respective dependent claims are patentably allowable.

Claims 4 and 13 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 3,740,604 to Zenick (*Zenick*). Dependent claim 4 depends from dependent claim 2 which depends from independent claim 1. Dependent claim 13 depends from independent claim 11. Therefore, claims 4 and 13 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

Claims 10 and 18 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 5,873,835 to Hastings et al. (*Hastings*). Dependent claim 10 depends from independent claim 1. Dependent claim 18 depends from dependent claim 14 which depends from independent claim 11. Therefore, claims 10 and 18 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view

of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: 4/24/06

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Melissa Stead 4-24-06

Melissa Stead Date

EXHIBIT D

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,877	12/19/2001	William Earl Webler	5618P2977	1005

8791 7590 05/23/2006

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Exhibit D

Office Action Summary

Application No.	Applicant(s)	
10/027,877	WEBLER, WILLIAM EARL	
Examiner	**Art Unit**	
Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-20 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-20 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 4 depend from a cancelled claim, therefore it is impossible to construe the scope of the claims. However, for the purposes of this examination, it has been assumed that claims 3 and 4 each depend from claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 5 – 9, 11, 12, 14 – 20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al.

5. In regards to claims 1, 3, 5 – 9, 11, 12, 14 – 20 and 26, Tay et al. discloses an elongate member as a needle, in that Tay et al. discloses the probe as a hollow elongated member (Col. 20, lines 12 – 18), or rod insertable into a body; a thermally conductive heating element coupled to the distal portion of the elongate member, the heating element comprising a wire whose electrical resistance changes in response to a change in temperature (Col. 20, lines 45 – 49). The needle

includes a distal opening, and a lumen (148; Figure 21) extending from a proximal end to the distal opening (Col. 16, lines 12 – 15) in communication with the distal opening capable of allowing a substance to be delivered through the lumen. The distal end of the needle is capable of puncturing skin (Col. 15, line 65 – Col. 16, line 1). Tay et al. discloses anemometry circuitry and comparing a first resistance and a second resistance of the at least one heating element to indicate a change of conditions related to a distance of penetration of the heating element (Col. 20, lines 48 – 54). Tay et al. discloses an outer diameter between 0.009 inches and 0.134 inches (Col. 19, line 56 – Col. 20, line 18). The heating element is less than the thickness of the tissue in which it is inserted. In order to operate the device as disclosed by Tay et al. must include a first and second lead coupled to the at least one heating element. However, Tay et al. fails to disclose the anemometry circuitry comprising the heating element and a variable resistor as resistive circuit element. Nor does Tay et al. disclose an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance. Lull et al. teaches a circuit for use in an anemometer (Col. 17, lines 10 - 15) comprising a balanced circuit (Col. 11, lines 40 – 46) having the heating element (R_1, R_2) and a variable resistor (Col. 7, lines 49 - 52) as resistive circuit element and an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance (Col. 7, line 25 – Col. 8, line 22). Lull et al. discloses anemometry circuitry separately coupled to each of the heating elements. It would have been obvious to one having ordinary skill in the art to modify the circuitry as disclosed by Tay et al. to include an interface to the balanced circuit as disclosed by Lull et al. in order to compare variations

in the resistance of the heating elements (Col. 17, lines 10 – 15). Tay et al. fails to disclose the heating element being between 0.010 inches and 0.400 inches. However, a change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),

cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

6. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 2 and 11 above, and further in view of U.S. Patent No. 3,470,604 to Zenick.

7. In reference to claims 4 and 13, Tay et al. in view of Lull et al. discloses a needle, but fails to disclose the needle being formed of stainless steel. However, stainless steel is well known in the medical industry for its strength, durability, ease of sterilization etc. Zenick discloses a hypodermic needle that is formed of stainless steel (Col. 1, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the needle as disclosed by Tay et al. in view of Lull et al. out of stainless steel as taught by Zenick in order to have a sturdy, durably and easily sterilized hypodermic needle for insertion into a patient.

8. Claims 10 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 5,873,835 to Hastings et al.

9. In regards to claims 10 and 18, Tay et al. in view of Lull et al. fails to disclose the forming the elongate member of an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member. Hastings et al. teaches a portion of the elongate member being electrically

conductive and the anemometry circuitry interface comprising an electrically conductive lead electrically coupled to a first end of the heating element, and the elongate member electrically coupled to a second end of the heating element (Col. 11, lines 33 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the elongate member as disclosed by Tay et al. in view of Lull et al. to be an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member as taught by Hastings et al. in order to reduce the resistance of the electrical connections to the heating element (Col. 11, lines 33 – 35).

Response to Arguments

10. Applicant's arguments filed 4/27/06 have been fully considered but they are not persuasive. In regards to the claims being rejected under 35 U.S.C. § 103 (a) as being obvious over US Patent No. 6,063,085 to Tay et al. in view of US Patent No. 6,539,792 to Lull et al., Applicant asserts that a prima facie case of obviousness has not been established. However the Examiner disagrees. As Applicant has pointed out, in order to establish a prima facie case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. The Examiner asserts that Tay et al. in view of Lull et al., when combined, teach or suggest all of the claim limitations (See Paragraph 5 above). The Examiner asserts that there is a reasonable expectation of success in that merely one anemometry circuit has been replaced by another. Each anemometry circuit as disclosed by Tay et al. and Lull et al. is used to compare a first resistance and a second resistance of at least one heating element. The

Examiner asserts that the suggestion or motivation to combine Tay et al. and Lull et al. is found in the references themselves or in the knowledge generally available to one having ordinary skill in the art. At Col. 20, lines 43 – 54, Tay et al. teaches that other techniques may be used to determine the depth of a vessel wall. Tay et al. suggests using a flow anemometer, which comprises two thin coils of wire spaced slightly apart on a probe and heated by passing electrical current there through, causing resistance heating. By constructing the coils out of wire with a temperature-dependent resistance, the position of the probe with respect to the vessel can be determined by comparing the resistance between the two coils, because blood flow past a coil within the artery will reduce its temperature, and hence its resistance, compared to a coil outside of the artery. However, Tay et al. fails to disclose any specific circuitry to control the anemometer. As a result, one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

EXHIBIT E

AF

IFW

Attorney's Docket No. 005618.P2977

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

William Earl Webler

Serial No. 10/027,877

Filed: December 19, 2001

For: Method and Apparatus for Determining Injection Depth and Tissue Type

Examiner: Jonathan M. Foreman

Art Unit: 3736

AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION

Mail Stop Amendments - No Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action dated May 23, 2006, Applicant requests entries of the Amendments and Remarks as set forth below.

Amendments to the Claims are reflected in the listing of claims and begin on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Exhibit E

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) An apparatus comprising:

a needle having dimensions suitable for insertion into a body, a distal portion suitable for insertion into tissue, a distal opening, and a lumen extending from a proximal end to the distal opening and in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening;

a thermally conductive heating element coupled to the distal portion of the ~~elongate member~~ needle, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an interface to a balanced circuit having the heating element and a variable resistor as resistive circuit elements, wherein the balanced circuit measures a first differential resistance between the heating element and the variable resistor in response to a first condition and a second differential resistance in response to a second condition in circuitry to indicate a change of conditions related to a distance of penetration of the thermally conductive heating element into a tissue.

2. (Canceled.)

3. (Currently Amended) The apparatus of Claim [[2]] 1, wherein the needle has an outer diameter between 0.009 inches and 0.134 inches.

4. (Currently Amended) The apparatus of Claim [[2]] 1, wherein the needle comprises a material of at least one of stainless steel and ceramic.

5. (Original) The apparatus of Claim 1, wherein the elongate member is a rod.

6. (Original) The apparatus of Claim 1, wherein the heating element comprises at least one of a wire, a film, and a thermistor material.

7. (Previously Presented) The apparatus of Claim 1, wherein the heating element has a length which is approximately equal to or less than the thickness of a tissue in to which at least a portion of the elongate member is to be inserted.

8. (Original) The apparatus of Claim 7, wherein the length of the heating element is between 0.010 inches and 0.400 inches.

9. (Previously Presented) The apparatus of Claim 1, wherein the interface is an anemometry circuitry interface comprising:

a first electrically conductive lead electrically coupled to a first end of the heating element; and

a second electrically conductive lead electrically coupled to a second end of the heating element.

10. (Previously Presented) The apparatus of Claim 1, wherein a portion of the elongate member comprises an electrically conductive material and wherein the interface comprises:

an electrically conductive lead electrically coupled to a first end of the heating element, and

the elongated member electrically coupled to a second end of the heating element.

11. (Previously Presented) An apparatus comprising:

a needle having dimensions suitable for insertion into a body, and having a distal end capable of puncturing skin;

a thermally conductive heating element coupled to a portion of the needle, the heating element comprising material whose electrical resistance changes in response to a change in temperature; and

an interface to electrically couple an anemometry circuitry to the heating element, wherein the circuitry comprises a balanced circuit having the heating element and a variable resistor as resistive circuit elements.

12. (Original) The apparatus of Claim 11, wherein the needle has an outer diameter between 0.009 inches and 0.134 inches.

13. (Original) The apparatus of Claim 11, wherein the needle comprises a material of at least one of stainless steel and ceramic.

14. (Previously Presented) The apparatus of Claim 11, further comprising anemometry circuitry electrically coupled to the heating element wherein the circuitry comprises a balanced circuit having a heating element and a variable resistor as resistive circuit elements, wherein the heating element comprises at least one of a wire, a film, and a thermistor material.

15. (Previously Presented) The apparatus of Claim 11, wherein the heating element has a length which is approximately equal to or less than the thickness of a tissue in to which at least a portion of the needle is to be inserted.

16. (Original) The apparatus of Claim 15, wherein the length of the heating element is between 0.010 inches and 0.400 inches.

17. (Previously Presented) The apparatus of Claim 14, wherein the anemometry circuitry is electrically coupled to a first end of the heating element by a first electrically conductive lead and is electrically coupled to a second end of the heating element by a second electrically conductive lead.

18. (Previously Presented) The apparatus of Claim 14, wherein a portion of the elongate member comprises an electrically conductive material and wherein the anemometry circuitry is electrically coupled to a first end of the heating element by an electrically conductive lead and is electrically coupled to a second end of the heating element by the elongate member.

19. (Previously Presented) The apparatus of Claim 14, wherein the anemometry circuitry comprises:

a circuit having the heating element and a variable resistor as resistive circuit elements; and

an amplifier electrically coupled to the circuit

to sense the difference in voltage drop across the heating element and the variable resistor caused by the difference between a first resistance of the heating element and a resistance of the variable resistor,

to amplify the voltage difference, and

to input the amplified voltage difference back to the circuit to cause a modification of a temperature of the heating element such that the heating element assumes a second resistance.

20. (Previously Presented) The apparatus of Claim 19, further comprising an additional heating element wherein the heating element and the additional heating element are coupled along a length of the elongate member, and further comprising:

anemometry circuitry separately coupled to each of the heating element and the additional heating element such that the heat dissipation characteristics measured by the plurality of anemometry circuits can be used to determine at least one of injection depth and tissue type.

21-25. Canceled.

26. (Previously Presented) The apparatus of Claim 11 wherein the needle has dimensions suitable for insertion into a tissue of the body and the balanced circuit is configured to measure a distance of penetration of the thermally conductive heating element into the tissue.

REMARKS

The office action dated May 23, 2006 (the "Office Action") has been received and carefully noted. Claims 1, 3-20 and 26 were examined. Claims 1, 3-20 and 26 were rejected. Claims 1, 3 and 4 are amended. The claims were amended to comply with 35 U.S.C. § 112. As such, no new matter has been added. Claims 1, 3-20 and 26 remain in the Application.

I. Claims Rejected Under 35 U.S.C. § 112

Claims 3 and 4 were rejected under 35 U.S.C. § 112 as being indefinite for depending on a cancelled claim. Claims 3 and 4 are amended to depend on currently pending claim 1. Applicant respectfully requests that the Examiner withdraw the rejection.

II. Claims Rejected Under 35 U.S.C. § 103

A.

Claims 1, 3, 5-9, 11, 12, 14-20 and 26 were rejected under 35 U.S.C. § 103 (a) as being unpatentable over in view of U.S. Patent No. 6,063,085 to Tay et al. ("*Tay*"), in view of U.S. Patent No. 6,539,792 to Lull, et al. ("*Lull*"). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More particularly, none of the cited references either singly or combined provide the suggestion or motivation to modify the references. The mere fact that the references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP 2143.01. Independent claim 1 is directed to "a needle coupled to a thermally conductive heating element, wherein the heating element is coupled to balanced circuit which measures a first differential resistance between the heating element and a variable resistor in response to a first condition and second differential resistance in response to a second condition to indicate a change of conditions related to a distance of penetration of the heating element into a tissue." Independent claim 11 is directed to "a needle

coupled to a thermally conductive heating element, wherein the heating element is coupled to a balanced circuit having two resistive circuit elements." According to the Application, a balanced circuit is capable of measuring heat dissipation characteristics of a tissue environment in which the heating element is disposed. Thus, independent claims 1 and 11 contemplate an apparatus for determining injection depth and/or tissue type based on the heat dissipation characteristics of body tissue. (App., p.2, lns. 9-11)

In contrast, *Tay* discloses an apparatus for closing and sealing a puncture at a puncture site in a vessel located beneath the skin using radio frequency or other energy to cauterize the puncture. (col. 2, lns. 45-47) *Lull* discloses a sensor that includes a first resistor, a second resistor, a first circuit, and a second circuit wherein the first and second resistors each has a resistance that varies in response to a change in a physical property. (Abstract) According to *Lull*, the sensor can be applied in semiconductor manufacturing processes and automotive applications. (col. 17. lns. 1-5) There is no suggestion in the cited references that it is desirable to combine a sensor which, according to *Lull*, can be used in semiconductor manufacturing processes and automotive applications with a vessel cauterizing medical device, as taught by *Tay*. The statement made by the Examiner that it would have been obvious to modify *Tay* in view of *Lull* "in order to compare variations in the resistance of the heating element" is merely a characteristic of the sensor described in *Lull* and is not a proper motivation to combine the cited references. (Office Action, p.4-5)

Moreover, the fact that a claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. MPEP 2143.01. In response to Applicant's previous arguments that a proper motivation to combine was not set forth, the Examiner states: "Tay et al. fails to disclose any specific circuitry to control the anemometer. As a result, one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer." (Office Action, p.6) The Examiner has provided no objective reason to combine *Tay* with *Lull*, but has merely made a generic statement that "one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer." The Examiner has not met his burden in providing a proper motivation to combine the cited references.

Furthermore, Applicant asserts that the Examiner has improperly combined the references because *Tay* teaches away from the claims. MPEP 2145(X)(D). A prior art reference must be considered in its entirety including portions that lead away from the claimed invention. MPEP 2141.02(VI). Independent claim 1 includes the limitation of "a needle having . . . a distal portion suitable for ***insertion*** into tissue . . . and a lumen extending from a proximal end to the distal opening and in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening." Independent claim 11 includes the limitation of "a needle having dimensions suitable for insertion into a body, and having a distal end capable of ***puncturing*** skin." Thus, the needle in Applicant's invention is either inserted into or punctures skin. By contrast, the cautery apparatus in *Tay* is designed to seal an already existing puncture wound in a vessel. (col. 5, lns. 10-62) Representatively, *Tay* discloses that the "present invention effects the hemostatic closure of a percutaneous or other type of puncture, incision or opening in a body vessel." (col. 5, lns. 45-57) Thus, *Tay* teaches away from independent claims 1 and 11 and therefore was improperly combined with *Lull*.

B.

Claims 4 and 13 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of Lull in further view of U.S. Patent No. 3,740,604 to Zenick ("*Zenick*"). Dependent claim 4 depends from dependent claim 2 which depends from independent claim 1. Dependent claim 13 depends from independent claim 11. Therefore, claims 4 and 13 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

C.

Claims 10 and 18 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of Lull in further view of U.S. Patent No. 5,873,835 to Hastings et al. ("*Hastings*"). Dependent claim 10 depends from independent claim 1. Dependent claim 18 depends from dependent claim 14 which depends from independent claim 11. Therefore, claims 10 and 18 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view

of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 1, 3-20 and 26, patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207-3800x766.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 6/29, 2006

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage thereon in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, Post Office Box 1450, Alexandria, Virginia 22313-1450, on 6-29, 2006.

Melissa Stead *6-29, 2006*

EXHIBIT F

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,877	12/19/2001	William Earl Webler	5618P2977	1005

8791 7590 10/26/2006

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EXAMINER	
FOREMAN, JONATHAN M	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Exhibit F

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/027,877	Applicant(s) WEBLER, WILLIAM EARL	
	Examiner Jonathan ML Foreman	Art Unit 3736	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *Claim 1 recites the new limitation "needle"*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

JMLF

Continuation of 11. does NOT place the application in condition for allowance because: In regards to the claims being rejected under 35 U.S.C. § 103 (a) as being obvious over US Patent No. 6,063,085 to Tay et al. in view of US Patent No. 6,539,792 to Lull et al., Applicant asserts that a prima facie case of obviousness has not been established. However the Examiner disagrees. As Applicant has pointed out, in order to establish a prima facie case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. The Examiner asserts that Tay et al. in view of Lull et al., when combined, teach or suggest all of the claim limitations (See Paragraph 5 above). The Examiner asserts that there is a reasonable expectation of success in that merely one anemometry circuit has been replaced by another. Each anemometry circuit as disclosed by Tay et al. and Lull et al. is used to compare a first resistance and a second resistance of at least one heating element. The Examiner asserts that the suggestion or motivation to combine Tay et al. and Lull et al. is found in the references themselves or in the knowledge generally available to one having ordinary skill in the art. At Col. 20, lines 43 - 54, Tay et al. teaches that other techniques may be used to determine the depth of a vessel wall. Tay et al. suggests using a flow anemometer, which comprises two thin coils of wire spaced slightly apart on a probe and heated by passing electrical current there through, causing resistance heating. By constructing the coils out of wire with a temperature-dependent resistance, the position of the probe with respect to the vessel can be determined by comparing the resistance between the two coils, because blood flow past a coil within the artery will reduce its temperature, and hence its resistance, compared to a coil outside of the artery. However, Tay et al. fails to disclose any specific circuitry to control the anemometer. As a result, one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer. .